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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,130	11/27/2001	David B. MacLean	PC11088ATMC	9834

7590 03/02/2005

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,130	MACLEAN, DAVID B.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted November 1, 2004 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacLean et al. (USPN 5,889,042), Carmeron et al. (USPN 5,552,412), Lund et al. (Testosterone and andropause, Pharmacotherapy 19 (8):951-6, August 1999) and Glass.

3. MacLean et al. (USPN 5,889,042) teaches a method of treating testosterone insufficiency employing (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8-tetrahydronaphthalen-2-ol, the elected specie herein. Administering the compound to elderly men result significant increase of testosterone level. See, particularly, the abstract, column 2, line 40 to column 5, line 41, and column 34, lines 15-57. Carmeron et al. teach the estrogen agonist/antagonist herein, including (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8- tetrahydronaphthalen-2-ol, and their use for treating diseases, including prostatic disease. See, particularly, the abstract, and the claims. The prostatic diseases therein are particularly defined as benign prostatic hyperplasia, or prostatic carcinoma. See, particularly, col. 8, lines 9-10. Lund et al. teaches that elderly men suffering from andropause with low levels of testosterone benefited from a testosterone replacement therapy, see abstract and page 953 in

particular. Lund et al. further teaches that steadily declining circulating testosterone levels in men suffering have andropause are implicated as a potential cause of symptoms and that restoring testosterone to physiological levels ameliorates symptoms associated with andropause. Glass. teaches that treating prostatic hypertrophy with testosterone is old and well-known. See, the entire documents, particularly pages 358. In summary, the primary references as a whole teach the usefulness of the estrogen agonist/antagonist herein and testosterone for treating andropause and prostatic hyperplasia. (note it is understood that prostatic hyperplasia is one of the two particular forms of prostatic hypertrophy) individually.

4. The primary references do not teach expressly the employment of the combination of testosterone with the estrogen agonist / antagonist.

However, it would have been obvious to one of ordinary skill in the art at the tome the invention was made to employ both (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8- tetrahydronaphthalen-2-ol, and testosterone in a method of treating benign prostatic hyperplasia in an andropausal male. One of ordinary skill in the art would have been motivated to employ both (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8-tetrahydronaphthalen-2-ol, and testosterone in a method of treating benign prostatic hyperplasia in an andropausal male because employing two agents that are individually known to be useful in treating andropause and prostatic hyperplasia in a method of treating the same is prima facie obvious. The Skilled Artisan would reasonably expect to obtain an additive effect by combining the two agents. Further, it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having

been individually taught in prior art; thus, the claimed invention which is a combination of two agents known for treating testosterone deficient, sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. One of ordinary skill in the art would have been further motivated to combine testosterone and an estrogen agonist in view of the teaching by Glass. Glass teaches the benefit of method of treating benign prostatic hypertrophy with combination of testosterone and estrogen. See the entire document, particularly, pages 362-363.

5. Claim 5 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacLean et al. (USPN 5,889,042), Carmeron et al. (USPN 5,552,412), Lund et al. (Testosterone and andropause, Pharmacotherapy 19 (8):951-6, August 1999) and Laroche et al., and in further view of Glass, for reasons discussed above, and in further view of Chiu et al. (US 5,948,809, IDS).

6. The references cited above as a whole do not teach expressly the tartrate salt of (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8- tetrahydronaphthalen-2-ol. However, Chiu et al. teaches that tartrate salt of (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8- tetrahydronaphthalen-2-ol is a pharmaceutical acceptable salt of tartrate salt of (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8- tetrahydronaphthalen-2-ol. See, particularly, the abstract and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the tartrate salt of (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8- tetrahydronaphthalen-2-ol as a pharmaceutical acceptable salt since tartrate salt of (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8- tetrahydronaphthalen-2-ol is a known pharmaceutical acceptable salt of (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-s,6,7,8- tetrahydronaphthalen-2-ol.

Response to the Arguments

Applicants' amendments and remarks submitted November 1, 2004 have been fully considered, but are moot in view of the new ground of rejections.

IDS

The supplemental IDS submitted November 1, 2004 has been received and were put in the file. However, the IDS has not been considered because the IDS does not satisfy the requirements set forth in 37 C.F.R. 1.97. See, MPEP 609.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617